KOH: USAO2012R00475

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
	*	
v.	*	**CRIMINAL NO.** GJH 15cr283
	*	
GAVIN BURNS SMITH,	*	**(Introduction of Misbranded Drugs**
	*	**Into Interstate Commerce With Intent**
Defendant	*	**to Defraud or Mislead, 21 U.S.C.**
	*	**§§ 331(a), 333(a)(2); Aiding and**
	*	**Abetting, 18 U.S.C. § 2; Forfeiture, 28**
	*	**U.S.C. § 2461(a), 21 U.S.C. §§ 334,**
	*	**853(p))**
	*	

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INDICTMENT

COUNTS ONE THROUGH SEVEN
(Introduction of Misbranded Drugs Into Interstate Commerce With Intent to Defraud or Mislead)

The Grand Jury for the District of Maryland charges that:

Introduction

At all times relevant to this Indictment:

1. The Food and Drug Administration ("FDA") was an agency of the United States Government charged with the responsibility of protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-397, to ensure that, among other things, drugs sold for use by or upon humans were safe and effective, and bore labeling containing accurate information and adequate directions for use. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs, drug components, and biological products introduced into interstate commerce.

2. The FDCA defined a "drug" as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals," and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1). A "new drug" was defined as any drug the composition of which is not generally recognized by experts as safe and effective for the use under the conditions prescribed, recommended, or suggested in the labeling. 21 U.S.C. § 321(p).

3. The FDCA provided that, before a new drug can be shipped in interstate commerce, its manufacturer first must obtain FDA approval of a New Drug Application ("NDA") for that drug. 21 U.S.C. §§ 355(a) and 331(d). The manufacturer of a new drug must have submitted information in the NDA showing to the FDA's satisfaction that the new drug was safe and effective for its intended use. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50.

4. The FDA enforced drug safety and efficacy standards by guarding against the misbranding of drugs. Under the FDCA, a drug was misbranded if its labeling was false or misleading in any particular. 21 U.S.C. § 352(a). Labeling included "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." 21 U.S.C. § 321(m). A drug was deemed misbranded unless its labeling bore, among other things: (1) truthful and non-misleading information; (2) adequate directions for use; and (3) adequate warnings against use in those with pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods of direction of administration application, in such manner or form as are necessary for the protection of users. 21 U.S.C. §§ 352(a) and (f).

5. The FDCA prohibited the introduction or delivery for introduction into interstate commerce (or the causing thereof) of any drug that was misbranded, 21 U.S.C. § 331(a), and any

new drug unless an application for that drug had been filed with the FDA, 21 U.S.C. §§ 331(d) and 355.

The Defendant

6. Defendant Gavin Burns **SMITH** was a resident of Florida, and owned and operated Precision Peptides ("Precision") and DNA Peptides ("DNA Peptides").

7. **SMITH** owned and operated Precision from at least in or about December 2010 through in or about April 2012. Precision operated out of 1642 Land O' Lakes Boulevard, Lutz, Florida, and advertised on the Internet through the website www.precisionpeptides.com ("the Precision website").

8. **SMITH** owned and operated DNA Peptides between in or about April 2012 through in or about May 2015. From between in or about April 2012 through at least in or about August 22, 2012, DNA Peptides operated out of 8022 Old Country Road 54, New Port Richey, Florida, and advertised on the Internet from the website www.dnapeptides.com.

9. On or about August 22, 2012, law enforcement executed search warrants issued by the United States District Court for the Middle District of Florida at Precision (1642 Land O' Lakes Boulevard, Lutz, Florida) and DNA Peptides (8022 Old Country Road 54, New Port Richey, Florida).

10. At some time after August 22, 2012, but prior to in or about March 2015, **SMITH** began operating DNA Peptides out of his residence at 8306 Night Owl Court, New Port Richey, Florida, and advertised on the Internet from the website www.dnapeptides.net (collectively, with www.dnapeptides.com, "the DNA Peptides websites").

11. Through Precision and DNA Peptides, **SMITH** sold body-enhancing injectable drugs to individual consumers seeking to enhance their physiques. The drugs that **SMITH** sold

through Precision and DNA peptides included, but were not limited to, Growth Hormone Releasing Peptide-2 ("GHRP-2"), Growth Hormone Releasing Peptide-6 ("GHRP-6"), Melanotan II, Growth Hormone Releasing Hormone ("CJC-1295"), Ipamorelin, Human Growth Hormone Fragment ("HGH Fragment"), Mechano Growth Factor, and Dehydroepiandrosterone ("DHEA"). These drugs were not approved by the FDA for use in humans.

12. **SMITH** caused the DNA Peptides and Precision websites to display numerous disclaimers stating that the products sold on the websites were "For Research/Laboratory Use Only." In addition, prior to purchasing any products from the DNA Peptides or Precision websites, each customer was asked to certify that the customer had read the following disclaimer: "The chemicals/materials for sale here are intended for laboratory and research use only, unless otherwise explicitly stated. They are not intended for human ingestion or for use in products that may be ingested." **SMITH** sold the products in vials that were labeled, "For Research/Laboratory Use Only" and "Not intended for human use."

The Charge

13. On or about each date listed below, in the District of Maryland and elsewhere, the defendant,

GAVIN BURNS SMITH,

with the intent to defraud and mislead, did cause the introduction into interstate commerce drugs that were misbranded under Title 21, United States Code, Section 352, in that their labels bore false and misleading labeling, to wit, the labels stated that the products were for research use

only, when in fact **SMITH** knew and fully intended that the products be used to affect the structure and function of the body.

COUNT	DATE	MAILING
1	November 21, 2011	Package containing four vials labeled "Sildenafil Citrate;" four vials labeled "GHRP-2;" one vial labeled "Melatonan II;" two vials labeled "CJC-1295;" and, one vial labeled "Myostatin Propeptide," mailed from 1642 Land O' Lakes Boulevard, Lutz, Florida to 14625 Baltimore Ave, Laurel, Maryland.
2	February 9, 2012	Package containing four vials labeled "CJC-1295 NO DAC;" sixteen vials labeled "GHRP-2;" four vials labeled "Ipamorelin;" and, four vials labeled "HGH Fragment," mailed from 1642 Land O' Lakes Boulevard, Lutz, Florida to 14625 Baltimore Ave, Laurel, Maryland.
3	May 2, 2012	Package containing four vials labeled "GHRP-2;" four vials labeled "CJC-1295 NO DAC;" two vials labeled "HGH Fragment;" and, four vials labeled "Ipamorelin," mailed from 8022 Old Country Road 54, New Port Richey, Florida to 14625 Baltimore Ave, Laurel, Maryland.
4	November 1, 2012	Package containing sixteen vials labeled "GHRP-2;" four vials labeled "CJC-1295 DAC;" four vials labeled "HGH Fragment;" and, four vials labeled "Ipamorelin," mailed from 8022 Old Country Road 54, New Port Richey, Florida to 5430 Lynx Lane, Columbia, Maryland.
5	April 17, 2013	Package containing one vial labeled "ACE-031;" one vial labeled "Follistatin;" four vials labeled "GHRP-2;" and, one vial labeled "PT-141," mailed from 8022 Old Country Road 54, New Port Richey, Florida to 5430 Lynx Lane, Columbia, Maryland.
6	August 5, 2013	Package containing two vials labeled "GHRP-6;" two vials labeled "CJC-1293;" one vial labeled "Follistatin;" and, one vial labeled "Ipamorelin," mailed from 8022 Old Country Road 54, New Port Richey, Florida to 10451 Twin Rivers Road, 288, Columbia, Maryland.
7	March 12, 2015	Package containing one vial labeled "Melanotan II;" four vials labeled "GHRP-6;" four vials labeled "CJC 1295 NO DAC;" two vials labeled "Sermorelin;" two vials labeled "TB-500;" and, two vials labeled "Triptorelin," mailed from 6306 Night Owl Court, New Port Richey, Florida to 10901 Rhode Island Avenue, Beltsville, Maryland.

21 U.S.C. §§ 331(a) and 333(a)(2)
18 U.S.C. § 2

FOFEITURE ALLEGATION

The Grand Jury for the District of Maryland further finds that:

1. Pursuant to Federal Rule of Criminal Procedure 32.2, notice is hereby given to the defendant that the United States will seek forfeiture as part of any sentence in accordance with Title 28, United States Code, Section 2461(a), and Title 21, United States Code, Sections 334 and 853(p), in the event of the defendant's conviction on any of Counts One through Seven of this Indictment.

2. As a result of the offenses set forth in Counts One through Seven of this Indictment, the defendant,

GAVIN BURNS SMITH,

shall forfeit to the United States of America, all property, real and personal, (a) which was used or intended to be used to commit the offense, or (b) which constitutes and is derived from proceeds traceable to the offense.

3. The property to be forfeited includes, but is not limited to, the following: a money judgment equal to the value of the proceeds of the charged offense, which amounts to at least $2,102,684.06 in United States currency.

4. If any of the property described above as being subject to forfeiture, as a result of any act or omission of any defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third person;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or,

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of said defendant up to the value of the forfeitable property, that is, at least $2,102,684.06.

28 U.S.C. § 2461(a)
21 U.S.C. §§ 334 and 853(p)

Rod J. Rosenstein | KOH
Rod J. Rosenstein
United States Attorney

A TRUE BILL:

SIGNATURE REDACTED
Foreperson

5/20/2015
Date